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September 23, 2008

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Julius Knapp
Chief, Office of Engineering & Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Re: ET Docket Nos. 06-135 and 05-213
Request for Extension of Waiver

Dear Mr. Knapp:

Pursuant to Section 1.925 of the Commission's rules,[1] DexCom, Inc. ("DexCom") hereby requests an extension of the Commission's waiver of the Medical Implant Communications Service ("MICS") rules until five years after the date on which the Commission concludes its MICS rulemaking proceeding.[2] Grant of this request will serve the public interest and ensure that the underlying purpose of the MICS rules is

[1] 47 C.F.R. § 1.925

[2] *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Notice of Proposed Rulemaking and Notice of Inquiry, ET Docket No. 06-135 (rel. July 18, 2006) ("NPRM"). In effect, grant of such a waiver would extend the present waiver period by only four years, since that waiver will expire one-year from the date upon which the Commission issues an adverse order in the pending MICS rulemaking proceeding. Of course, to the extent that the new MICS rules are not adverse to DexCom but are modified in a way that would allow DexCom to continue its present operations without a waiver, DexCom would not require an extension of its present waiver.

not frustrated, as it will allow diabetes patients continued access to DexCom's highly effective continuous glucose monitoring system.

Operation of DexCom's System under the Terms of the Present Waiver

More than two and a half years ago, in January 2006, the Commission granted DexCom a waiver of the MICS rules to allow its continuous glucose monitoring ("CGM") devices to operate without employing a listen-before-transmit ("LBT") protocol.[3] Since that time, DexCom has been operating successfully under the terms of the waiver. Thousands of people suffering from diabetes have benefited from using DexCom's technology and there have been no reported instances of harmful interference or other problems associated with use of DexCom's technology pursuant to the waiver.

The medical community values DexCom's system because of the clinical advantages resulting from CGM. DexCom's implantable sensors measure a patient's glucose level every five minutes, allowing diabetics to react quickly to changing glucose levels and maintain far more consistent glucose levels than with other methods.[4] Studies have shown that, with use of the DexCom system, patients' time spent in the "normal" range increased by 88%, thereby enabling diabetics to avoid many of the serious complications of the disease.[5] DexCom subsequently participated in a large clinical study with the Juvenile Diabetes Research Foundation ("JDRF") to show the benefits of CGM. In a presentation on September 8, 2008, JDRF announced that patients who used CGM devices for at least six days per week achieved significant reductions in HbA1c levels, the most widely accepted indicator of long-term glucose values in the blood.[6]

In addition to its present system, DexCom is working with several manufacturers of insulin pumps to develop integrated systems that combine CGM technology with

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[3] *In the Matter of DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 21 FCC Rcd 875 (2006) ("DexCom Waiver"). The waiver expires "three years from the release date of this Order [*i.e.,* Jan. 18, 2009] or until one year after completion of any rule making the Commission may under take, whichever is later." Id. at ¶ 22. Because the Commission has not yet completed its MICS rulemaking proceeding, the latter date applies.

[4] *See In the Matter of DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Request for Waiver, ET Docket No. 05-213 (filed May 23, 2005) ("DexCom Waiver Request").

[5] *Id.*

[6] *See* e.g. Robert Tomsho, *Adult Diabetics Benefit from Device, Study Says,* Wall Street Journal, September 9, 2008, at D2 (discussing results of the JDRF study).

insulin pumps.[7] These devices will give diabetics the ability to monitor their glucose levels and administer insulin using just one device, which will provide greater ease of use for the patient. DexCom estimates that, by mid-2009, the first integrated systems will be available and that many thousands of patients will begin using them. The lifespan of these new DexCom devices is expected to be approximately three years.

JDRF supports the development of such integrated systems through its Artificial Pancreas Program and is investing funds to support research. DexCom anticipates that, upon detection of very low glucose levels by a CGM sensor, integrated devices may be programmed to direct an insulin pump to automatically stop delivery of insulin to the patient, and to increase insulin flow to the patient upon detection of high glucose levels.

In summary, the present waiver has promoted the public good by allowing the medical community to use DexCom sensors with diabetic patients, providing considerable proven medical benefits. With the upcoming release of the integrated systems, even greater numbers of patients will experience a fuller range of benefits.

Need for Extension of the Waiver

DexCom's existing waiver is due to expire one-year from the date upon which the Commission issues an order in the pending MICS rulemaking proceeding that is adverse to DexCom.[8] In that rulemaking, the Commission is considering whether to modify the MICS rules to allow low-power, low-duty cycle devices such as DexCom's to operate without LBT, either in the main band or in the proposed side bands.[9] DexCom has urged the Commission to adopt rules allowing non-LBT devices with operating characteristics similar to DexCom's sensors to operate on at least one channel in the main MICS band.[10] DexCom has explained that it would be unable to operate its system if the Commission adopts new rules that limit the allowable output power of its devices.[11]

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[7] These devices will employ the exact same transmitter, operating under the same conditions, as the transmitter approved by the Commission in granting the waiver. Thus, DexCom does not require a change in the terms of the present waiver to market these devices.

[8] DexCom Waiver at ¶ 22 and n.3, *supra*.

[9] NPRM at ¶ 24.

[10] *See In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Comments of DexCom, Inc. at 3, ET Docket No. 06-135 (filed October 31, 2006) ("DexCom NPRM Comments").

[11] *Letter to Marlene H. Dortch from Henry Goldberg, Re: Notice of Ex Parte Presentation*, ET Docket No. 06-135 (filed Feb. 28, 2008) ("DexCom 2008 Ex Parte Presentation").

At present, it appears that a consensus position has developed both in the United States and internationally to allow certain non-LBT devices to operate on the center MICS frequency of 402-405 MHz.[12] Proposals also have been made to permit non-LBT devices to operate on newly allocated side bands.[13] As DexCom has discussed with the Office of Engineering and Technology ("OET") staff, however, neither of the present proposals before the Commission would allow DexCom to operate without a waiver, as the power level of the DexCom device exceeds the power levels in these proposals.[14] Specifically, DexCom operates at a power level close to 10 uW EIRP (-20dBm) EIRP, while the apparent consensus proposal would allow non-LBT devices to operate at power levels no greater than 100 nW ERP on the main MICS band and 250 nW EIRP on the side bands.[15]

An output power of 250 nW is not feasible for operation of the present DexCom device, a problem that would be compounded considering DexCom's planned integrated glucose monitor and insulin pump device, which requires even greater power to achieve necessary range. Indeed, a power reduction to 250 nW would reduce the effective range of DexCom's technology to less than two feet, making the device unusable for its therapeutic purposes.[16]

Accordingly, DexCom may be forced to consider transitioning out of the MICS band should the results of the rulemaking be adverse to its needs. DexCom could not make such a transition, however, within the period permitted by its present waiver,

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[12] *See Letter from David E. Hilliard to Julius Knapp, Chief, Office of Engineering and Technology, Federal Communications Commission*, ET Docket No. 06-135 and RM-11271 (Jan. 10, 2008) ("Medtronic Ex Parte").

[13] *See In the Matter of Amendment of Parts 2 and 95 of the Commissions' Rules to Establish the Medical Data Service at 401-402 and 405-406 MHz*, Petition for Rulemaking, RM No. 11271 (filed July 15, 2005).

[14] DexCom 2008 Ex Parte Presentation at 7. This *ex parte* presentation to the OET staff, which was filed in the rulemaking docket, summarizes DexCom's position. DexCom is attaching that presentation herein to make the waiver record complete.

[15] *See, e.g., Letter to Marlene H. Dortch from Henry Goldberg, Attorney for Biotronik, Inc.*, ET Docket Nos. 06-135 & 05-213 and RM-11271 (filed Feb. 27, 2008) and NPRM at ¶ 25. Additionally, ETSI adopted new standards imposing a similar power level restriction for non-LBT devices operating on the center MICS channel of 100 nW EIRP. *See* ETSI EN 301 839-1 v1.2.1 (2007-04).

[16] While it may be true that some types of MICS systems can operate at a 250 nW power level, DexCom's system cannot. The DexCom system uses a small, handheld receiver, which is far easier for a patient to transport but creates constraints in antenna design and efficiency. Other systems also can increase the reliability of their RF link by repeating their few daily transmissions to ensure that the data is received. This method is not possible in DexCom's system because new information is transmitted every five minutes and battery constraints do not permit what would be virtually continuous repeat messages.

including the anticipated one-year period from the end of the instant rulemaking proceeding. DexCom estimates that it would take up to five years to develop, test and receive regulatory permissions for a range of products not dependent on the MICS band. DexCom therefore requests a five-year extension of its waiver from the conclusion of this proceeding, should the new rules not allow it to continue to operate on the MICS band.[17]

A Five-Year Extension is Reasonable and Would Serve the Public Interest

Five years is a reasonable period for the Commission to extend its waiver. First, grant of this extension would extend the waiver period by a period of only four years.[18] Additionally, the redesign that would enable DexCom to cease operating in the MICS band would require a significant amount of time. That redesign process includes the following sequential steps: (i) collaborate with each of its insulin pump partners to determine the appropriate RF frequency and design specifications; (ii) develop a new transmitter and receiver; (iii) design a verification testing process; (iv) engage in internal verification and validation testing; and (v) plan and engage in clinical trials. At the completion of this process, DexCom then would have to secure the approval of the Federal Drug Administration ("FDA"), which is a very time consuming and rigorous regulatory review process that could take over a year to complete once DexCom's application is submitted. Even after FDA approval is obtained, it would be several more months before DexCom patients would have access to the new products since commercial launch would require the coordinated efforts of DexCom and its insulin pump partners.

DexCom believes that a five-year extension of its waiver would provide it the time to complete this process and introduce new technology that would allow it to leave the MICS band. Moreover, within this timeframe, most of the DexCom devices permitted under the waiver would complete their useful life.

For several reasons, grant of this extension would not impose any risk of interference by or to other MICS devices. In granting the present waiver to DexCom, the Commission found that the risk of certain non-LBT devices, including DexCom's, causing harmful interference to other MICS devices, or receiving harmful interference, is negligible.[19] This remains true.

DexCom's transmitters operate on a single channel within the MICS band and were designed specifically for ultra-low duty cycle operation to mitigate any possible

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[17] Additionally, DexCom notes that it would require the ability to perform warranty replacement services for a period of time after the end of the waiver period.

[18] *See* n.2, *supra*.

[19] DexCom Waiver at ¶ 16 (finding that the "combination of bandwidth, power, and duration make the likelihood of causing interference virtually nil.").

interference. The transmission time of a DexCom transmitter is 10 ms per 5 minutes, or 120 ms per hour, which is less than half of the 360 ms per hour that is being proposed for use in the center of the MICS band.[20]

DexCom's transmissions pose no more possibility of interference than what is being proposed for use in the center of the MICS band. In fact, with a total duty cycle of 0.003%, a DexCom transmitter has far less transmission time than the 0.01% total duty cycle that the other manufacturers, including Medtronic, already have agreed to use in the center of the MICS band. Given the already ultra low-power of DexCom's system, lowering the output power would do little to mitigate the threat of interference. Since a DexCom transmitter transmits only for 10 ms every 5 minutes, for 99.99% of the time there are no transmissions and therefore no chance of causing any interference. In sum, the operating parameters of the DexCom system do not pose a threat of interference to other devices.

Moreover, because the MICS band continues to be lightly used and because the Commission is likely to allocate additional spectrum for medical implant devices, the grant of a five-year waiver to DexCom would not pose any threat to the operations of other MICS devices.[21] Even if use of the band increases greatly over these years, the Commission has determined that, given the "proximity of the receiver to the transmitter, it is also highly unlikely that another MICS device will be sufficiently close to cause interference to a DexCom device while attempting to transmit at the same moment and on the same frequency as the DexCom device."[22]

Accordingly, an extension of DexCom's waiver will ensure that diabetics will continue to have access to an extremely effective and beneficial tool until DexCom is able to redesign new technology, should that prove necessary. DexCom requests that devices allowed under the terms of this requested waiver be allowed to continue operating for a five year period measured from the end of the rulemaking proceeding.

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[20] And according to a peer-reviewed paper submitted by Biotronik in the rulemaking proceeding, the threat of interference in that situation is extremely small. *See Letter to Marlene H. Dortch from Henry Goldberg, re ET Docket Nos. 06-135 & 05-213 and RM-11271, Notice of Ex Parte Presentation* (filed Sept. 25, 2007).

[21] DexCom notes that, in addition to the additional spectrum that the Commission is considering allocating in the MICS band, a rulemaking petition has been filed requesting the allocation of spectrum in the 2360-2400 MHz band for medical device use. *See Office of Engineering and Technology to Treat Ex Parte Comments of GE Healthcare as Petition for Rulemaking and Seeks Comment*, Public Notice ET Docket No. 08-59 (rel. April 24, 2008).

[22] *Id*.

Please direct any questions concerning this matter to the undersigned counsel.

Sincerely,

Henry Goldberg
Laura Stefani
Attorney for DexCom, Inc.

cc: Julius Knapp
Bruce Romano
Alan Stillwell
Geraldine Matise
Jamison Prime
Gary Thayer
Mark Settle

DexCom Comments on MICS/MEDS NPRM

ET Docket Number 06-135

February 27, 2008

Meeting Objectives

- Diabetes Overview
  - Overview of DexCom™ STS® Continuous Monitors
  - Update on Seven™
  - Insulin Pump integration agreements
- Problems with proposal to reduce output power
- DexCom needs a rule change consistent with the present waiver

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Everyday in the US…

- 1 in 3 children born will develop diabetes
- 4,100 people will be diagnosed
- 55 people with diabetes will go blind
- 230 amputations will be performed
- 120 will enter treatment for kidney failure

1 in 7 health care dollars is spent treating diabetes

Kleinfeld N.R. NYT, "Diabetes and Its Awful Toll Quietly Emerge as a Crisis" 1/9/2006

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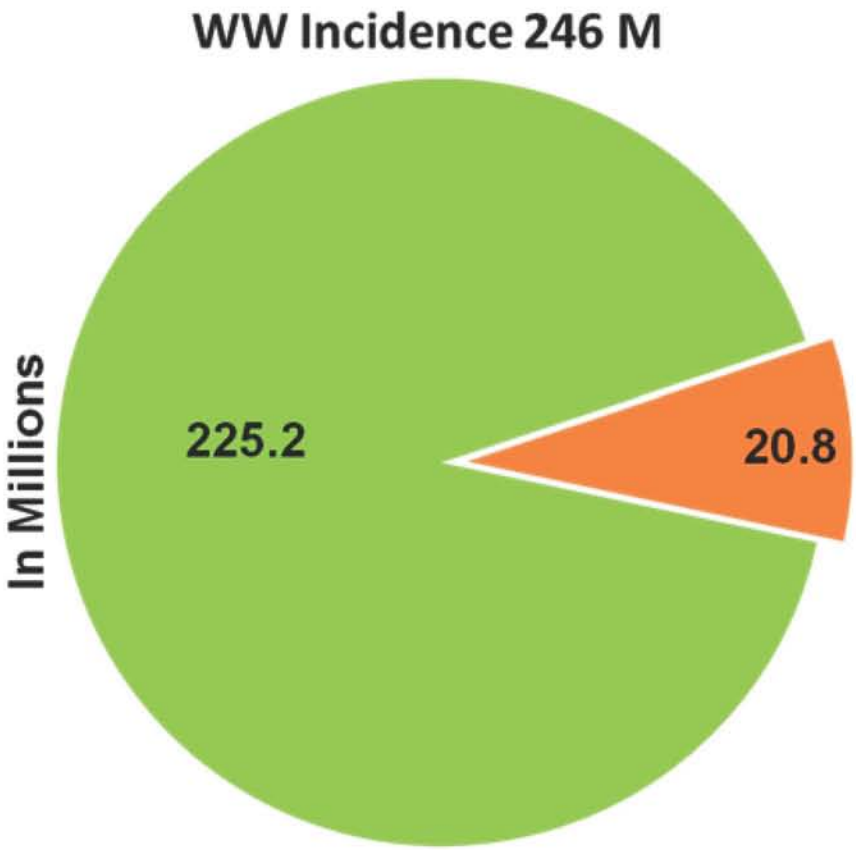
Diabetes: A Global Epidemic



US Incidence 20.8 M

6.2

Undiagnosed

14.6

IDF estimates 380M by 2025

ADA estimates 23.9M by 2011

Source: IDF website “Facts & Figures”

ADA website “Diabetes Fact Sheet”

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Take control–live u

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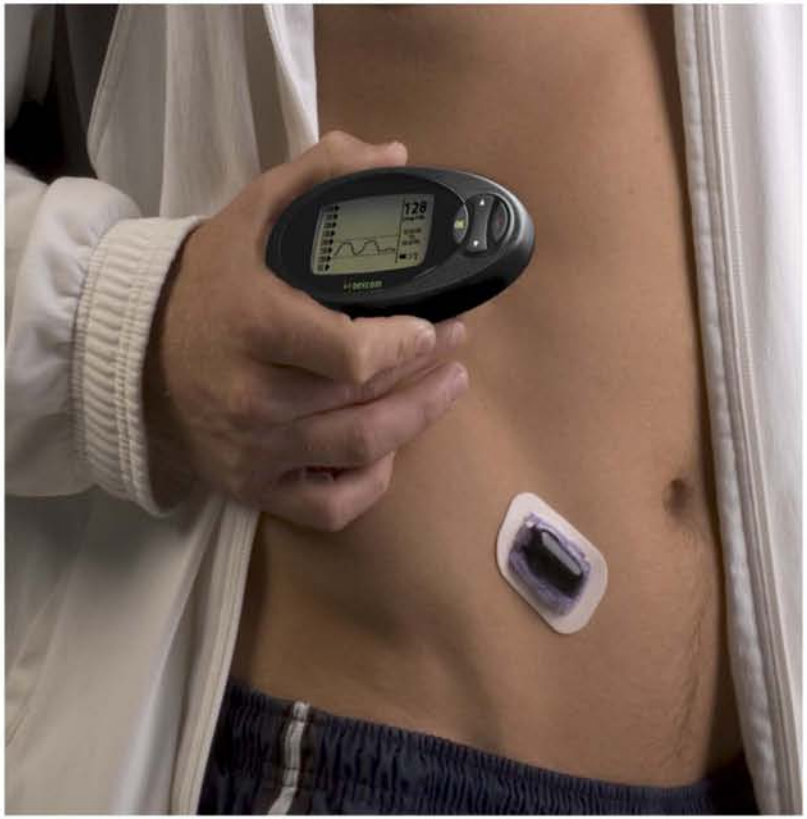
Take control–live uninterrupted.™



The Sensor

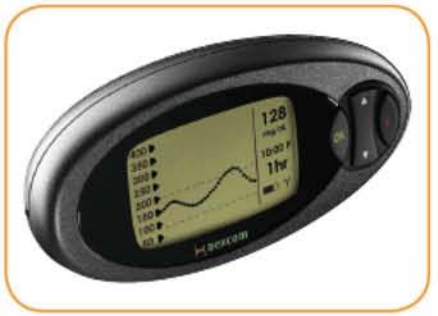
- Small & Comfortable
- Water Resistant
- The Only 7 day Sensor

The Transmitter

- Wireless
- Unique Micro-technology

The Receiver

- Portable & Lightweight
- Trending Screens
- High & Low Glucose Alerts



SEVEN System Update

- Outreach efforts continue in approximately 100 largest diabetes centers in the U.S.
  - Continue to see increase in the number of new patients added in these key centers
  - Continue to invest in activities to gain acceptance of CGM as the best standard of care for diabetes management
  - DexCom is actively working with the JDRF (Juvenile Diabetes Research Foundation) on a long term clinical trial to show the benefits of Continuous Glucose Monitoring.
- The next challenge is widespread insurance reimbursement

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DexCom Takes First Steps Towards a Closed Loop System

- DexCom has signed two agreements to develop integrated insulin pump-CGM systems with J&J/Animas and Insulet
  - DexCom CGM data to be displayed on Insulin Pump
  - Trended information and glucose alarms included
  - Allows for insulin dosing information and CGM data on same display, therefore, reliable communication is essential
- JDRF is strongly supporting the development of closed loop systems

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Proposal to Reduce Output Power Will Render DexCom STS Unusable by Patients

	Current MICS Design	Proposed MedRadio Design
Receiver Noise Floor	**-97dBm**	**-97dBm**
Receive Antenna Gain	**-2dBi**	**-2dBi**
Required SNR	**14dB**	**14dB**
Fade Margin	**10 dB**	**10 dB**
Excess Loss (Polarization, obstructions)	**15 dB**	**15 dB**
Body Absorbtion	**4 dB**	**Accounted for in EIRP Test**
EIRP	**-20 dBm**	**-36 dBm**
Allowable Free Space Path Loss	**32 dB**	**20 dB**
Useful Operating Range	**7.5 ft**	**1.9 ft**

- Reducing the output power of the DexCom STS transmitter would dramatically decrease the effectiveness of the system. To require patients to keep the handheld Receiver or integrated Insulin Pump less than two feet from the body worn Transmitter to ensure reliable communication is not realistic.
- Insulin Pump manufacturers require a communication distance of at least five feet.

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DexCom Requests that Current Waiver Be Adopted as Rule for MICS Band

- Fixed operation on channel 1 of MICS band
- Standard MICS output power of 25uW
- Non-LBT operation with ultra low duty cycle of 0.003%

dexcom